REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the following remarks.

Claims 1-37, 44, 46-63 and 74-89 are pending in the subject application.

Claims 38-43, 45 and 64-73 were previously canceled. These claims were withdrawn from consideration as the result of an Examiner's earlier restriction requirement. In view of the Examiner's restriction requirement, Applicants reserve the right to present the above-identified withdrawn claims in a divisional application.

Claims 1, 37, 46-63 and 74-89 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §103.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, 47-48, 52-55, 57-58, 61-62 and 75-76 under 35 U.S.C. §102(b) as being anticipated by Chosack et al. [WO 99/38141; "Chosack"]. Applicants respectfully traverse.

Applicants first note that Chosack had been cited earlier during prosecution also in connection with a prior §102(b) rejection. In response to Applicants prior amendments and remarks the prior rejection under §102(b) based on Chosack was withdrawn. As the presently pending claims would appear to be narrower in scope than the earlier claims where the rejection had been withdrawn, Applicants would submit that the present claims remain distinguishable from Chosack. Notwithstanding the foregoing, Applicants offer the following additional observations.

Applicants set forth in claim 1 a simulator system including a manikin and a medical device, where the simulator system simulates the use and movement of the medical device in a simulated body cavity or lumen of the manikin.. The medical device includes a first end for manipulation by a first user and a portion having a second end insertable into a simulated body

cavity or body lumen in a manikin.

The manikin includes an interface device that is configured to receive the medical device portion having the second end and to interface with the simulated body cavity or lumen. The interface device also includes an active directional force feedback mechanism that exerts a directional force on the medical device in response to a feedback signal received by the force feedback mechanism.

The system also includes a computational engine embodying physically based modeling using finite element methodology. The computational engine simulates interactions between the medical device and body cavity or lumen, the interactions relating to the manipulation of the medical device by the first user. The computational engine models interactions between the medical device and the body cavity or lumen in three-dimensions, computes forces that would arise from interactions between the medical device and body cavity or lumen and outputs feedback signals corresponding to the computer forces to the active directional force feedback mechanism so as to thereby feedback said computed forces to the user.

The system according to the invention, such as that for example set forth in claim 1 above, and the methods of using, as claimed, rely on the use of physically based modeling embodying finite element methods to simulate interactions between a medical device and body cavity or lumen, providing highly realistic visual and tactile feedback when a user interacts virtually with the system to practice or implement a medical procedure. The physical properties of both the device and the lumen are taken into account by a computational engine or processor of the claimed invention in a physically based modeling procedure.

Chosack does not describe, teach or suggest the use of such physically based modeling embodying finite element methods. Although using animation to mimic certain processes such as blood flow and deformation, Chosack does not use a physically based finite element modeling system that calculates the amount of force that would be exerted as a result of interactions between a medical device and body cavity or lumen to provide force feedback to a user of the simulation system in addition to visual feedback; Chosack merely describes providing real-time

visual feedback. Further, Chosack does not disclose altering the parameters of a finite element model of a device or body cavity or lumen in response to a user's interactions with the device.

While elements shown in Chosack might resemble an endoscopic view of a simulator according to the present invention and while there are words and phrases appearing in the subject application and Chosack, the process and technical details are very different.

The system or simulator described in Chosack is similar to other conventional technologies like a "nose(sinus)" simulator including a dummy head with sensors placing all over the airways from the nose. When using such a dummy head, the trainee would insert a pair of scissor towards a target area displayed as images/models on a computer monitor. This is similar to the same endoscopic view shown in Chosack except that it is the airway and not the intestine.

The system in Chosack is essentially an electromechanical system. Actual video data is taken and processed in advance to extract the individual frames. In the present invention, the simulation system embodies use of more of the virtual reality technology, where the main components are with the numerical models in the form of software. Volume data (CT/MRI) are processed to generate the video that is used in the teaching. The way models are constructed and force, visual are feedback are rather different between Chosack and the presently claimed invention.

Like conventional technologies which relies on sensors placing over a physical structure, the training described in Chosack is not patient specific. For example, what if one wanted to try a procedure on a child, but the simulator is built according to the size of an American adult. For the simulator system described in Chosack, one would need a to create a physical simulated organ that was properly sized for the child (*e.g.*, weight, age size) and then locate this properly sized organ in the manikin.

A closer comparison between the present invention and Chosack also reveals that the actual engineering is obviously different. For example, in the present invention it is not necessary to build a "physical" simulated organ that is disposed within the manikin. In the

present invention, the simulated organ is "virtual," where the boundary of the organ is represented using numbers and deformation is "computed" using finite element method with "measured" mechanical properties of vessels.

The Office Action also refers to discussion on pages 10 and 23 of Chosack as disclosing features of the claimed invention including *inter alia* an active force feedback device that exerts a force on the medical device, and a computational engine embodying physical based modeling to simulate interactions between the medical device and the body cavity or lumen. Applicants respectfully disagree.

The discussion on page 10 provides that the simulated gastrointestinal tract includes a tactile feedback system that provides tactile feedback according to the movement of the simulated endoscope within the physically simulated organ. As indicated herein, in Chosack, the organ is a physical representation of the organ being simulated, not a virtual organ.

As also described in Chosack, the endoscope is configured with a locator 60 that receives information as to the location of the endoscope (*e.g.*, the tip of the endoscope) within the simulated organ inside the manikin (*e.g.*, see pg. 18, l. 9-20 thereof) It is further provided in Chosack, that the locator includes a sensor 76 and that this sensor senses positional information within the simulated organ 77 (in Chosack reference is made to a colon as the simulated organ). Chosack provides a more detailed discussion of how the position of the endoscope position is determined on page 21 (see lines 18-31).

The sensor 76 also is controlled by a control unit 83 and the positional information is relayed to a CPU controller 78, which in turn is connected to a servo-motor 80. Chosack also describes that as the simulated colon moves through the colon, it contacts different portions of the colon. Tactile feedback is provided by each servo-motor 80 which manipulates the material of the colon. See pages 19 and 23 of Chosack. The discussion referred to on page 23 of Chosack, refers to Figures 6A-6C thereof. It is clear from the discussion on pages 22-23, that a plurality of motion boxes 134 are arranged at intervals along the outer surface of the gastro-intestinal tract, where each motion box includes at least one and preferably a plurality of servo-

motors 80. Each servo-motor 80 is connected to a piston 136 which also is connected to a foot 138 which is contact with a portion of the material of the external surface of the gastro-intestinal tract. In this way, the attached foot 138 can manipulate this material so a force is exerted against the endoscope. It is further described in Chosack that software operated on the PC uses the positional and orientation information from the sensor 76 to determine the position of the endoscope.

Thus, it can be seen form the forgoing remarks that Chosack does not describe, teach or suggest a simulator system such as that of claim 1 and more particularly, Chosack does not disclose an interface device that includes an active directional force feedback mechanism that exerts a directional force on the medical device in response to a feedback signal received by the force feedback mechanism; a computational engine embodying physically based modeling using finite element methodology that simulates interactions between the medical device and body cavity or lumen, the interactions relating to the manipulation of the medical device by the first user; and wherein the computational engine models interactions between the medical device and the body cavity or lumen in three-dimensions, computes forces that would arise from interactions between the medical device and body cavity or lumen and outputs feedback signals corresponding to the computer forces to the active directional force feedback mechanism so as to thereby feedback said computed forces to the user.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051; 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by Chosack.

Accordingly, because the reference does not teach each element of the claims as required under 35 U.S.C. § 102(b), Applicants respectfully submit that the rejection should be withdrawn.

It is respectfully submitted that for the foregoing reasons, claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, 47-48, 52-55, 57-58, 61-62 and 75-76 are patentable over the cited reference and satisfy the requirements of 35 U.S.C. §102(b). As such, these claims, including the claims dependent therefrom are allowable.

35 U.S.C. §103 REJECTIONS

Claims 49 and 77-87 stand rejected under 35 U.S.C. §103 as being unpatentable over Chosack et al. [WO 99/38141; "Chosack"] in view of Cai et al., Parametric Modeling Based on Multi-Layered Approach for Design and Validation of Catheterization Devices [citations omitted; "Cai"]; claims 7, 8, 63, 74, 88 and 89 stand rejected as being unpatentable over Chosack in view of Rosenberg et al. [U.S. Patent 5,959,613; "Rosenberg"]; claims 12-15 stand rejected as being unpatentable over Chosack in view of Belson, et al. [U.S. Patent 6,610,007; "Belson"]; claims 24 and 32 stand rejected as being unpatentable over Chosack in view of Simon et al. [U.S. Patent 6,470,207; "Simon"] and Saunders [U.S. Patent 6,572,376]; 26, 27, 29 and 56 stand rejected as being unpatentable over Chosack in view of Pollak, et al. [U.S. Patent 66,106,297; "Pollak"] and Issenberg, et al. Simulation Technology for Health Care Professional Skills Training and Assessment [citations omitted; "Issenberg"]; claim 36 stands rejected as being unpatentable over Chosack in view of Pollak, et al. [U.S. Patent 6,106,297; "Pollak"] and Issenberg, et al. Simulation Technology for Health Care Professional Skills Training and Assessment [citations omitted; "Issenberg"] and further in view of Hon [U.S. Patent 6,074,213]; and claims 44, 46, 50, 51, 60 and 59 stand rejected as being unpatentable over Chosack in view of Merrill [U.S. Patent 6,106,301] for the reasons provided on pages 9-19 of the above-referenced Office Action.

It is respectfully submitted that each of the foregoing claims is considered to be patentable over the identified combination of references as the primary reference does not

disclose the claimed invention and the secondary, tertiary, etc. references do not make up for the deficiencies in the primary reference identified in the discussion concerning the §102(b) rejection. As such, at least for this reason each of the above-identified claims is considered to be patentable over the identified combination of references. These brief remarks, however, shall not be construed as an admission that these claims are not otherwise patentable over the cited art.

Applicants also would note that in the Final Office Action, claim 44 was an objected to with a further indication that this claim would be allowable if appropriately re-written in independent form. The art of record in the above-referenced Office Action is the same art that had been considered in connection with the Final Office Action.

As previously indicated by Applicants, in contrast to the present invention the secondary reference, Rosenberg, describes and teaches a method and apparatus for shaping force signals (*i.e.*, an impulse-shaped force signal) for a force feedback mechanism.

As also previously indicated, Belson does not teach the use of physically based finite element modeling and does not disclose the use of perpendicular sensors nor provide any motivation to use such sensors.

As also previously indicated by Applicants, Simon and Saunders do not teach the use of physically based finite element modeling; Pollak does not teach the use of physically based finite element modeling; and Merril does not teach the use of physically based finite element modeling.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 19866). Additionally, it also has been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding the disclosures of the cited references, there is no reasonable expectation of success provided in the reference(s). Also, it is clear from the foregoing discussion that the modification suggested by the Examiner would change the principle of operation of the device disclosed in the principal reference.

Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills* , 916 F. 2d, 680, 682; 16 USPQ 2d 1430, 1432 (Fed. Cir. 1990). As the Federal circuit also has stated, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260,1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992).

It is respectfully submitted that for the foregoing reasons, claims 7, 8, 12-15, 24, 26, 27, 29, 32, 36, 44, 46, 49-51, 56, 59, 60 63, 74, and 77-89 are patentable over the cited reference(s) and thus, satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within

Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

Edwards Angell Palmer & Dodge, LLP

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William J. Daley, Jr.
(Reg. No. 35,487)
P.O. Box 55874
Boston, MA 02205
(617) 439- 4444

Customer No. 21,874

Bos2_568250